Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive:
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Nivolumab (new therapeutic indication: non-small cell lung cancer, PD-L1 expression ≥ 1%, neoadjuvant and adjuvant treatment, monotherapy or combination with platinum-based chemotherapy)

of 4 December 2025

At their session on 4 December 2025, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. **In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Nivolumab in the version of the resolution of 4 December 2025 on the therapeutic indication "First-line therapy of unresectable or advanced hepatocellular carcinoma":**

Nivolumab

Resolution of: 4 December 2025
Entry into force on: 4 December 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 May 2025):

OPDIVO, in combination with platinum-based chemotherapy as neoadjuvant treatment, followed by OPDIVO as monotherapy as adjuvant treatment, is indicated for the treatment of resectable non-small cell lung cancer at high risk of recurrence in adult patients whose tumours have PD-L1 expression ≥ 1%.

Therapeutic indication of the resolution (resolution of 4 December 2025):

See new therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Adults with resectable non-small cell lung cancer at high risk of recurrence and whose tumours have PD-L1 expression ≥ 1%; neoadjuvant and adjuvant treatment

Appropriate comparator therapy:

Neoadjuvant treatment:

Pembrolizumab in combination with platinum-based therapy

Followed by adjuvant treatment:

Pembrolizumab

Extent and probability of the additional benefit of nivolumab compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults with resectable non-small cell lung cancer at high risk of recurrence and whose tumours have PD-L1 expression ≥ 1%; neoadjuvant and adjuvant treatment

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-81) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with resectable non-small cell lung cancer at high risk of recurrence and whose tumours have PD-L1 expression ≥ 1%; neoadjuvant and adjuvant treatment

Approx. 3,240 to 3,680 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Opdivo (active ingredient: nivolumab) at the following publicly accessible link (last access: 28 November 2025):

https://www.ema.europa.eu/en/documents/product-information/opdivo-epar-product-information_en.pdf

Treatment with nivolumab should only be initiated and monitored by specialists in internal medicine, haematology and oncology who are experienced in the treatment of patients with non-small cell lung cancer, as well as specialists in internal medicine and pulmonology or specialists in pulmonary medicine and other doctors from other specialist groups participating in the Oncology Agreement.

In accordance with the EMA requirements regarding additional risk minimisation measures, the pharmaceutical company must provide training material that contains information for medical professionals and patients (including patient identification card).

The training material contains, in particular, information and warnings about immune-mediated side effects as well as infusion-related reactions.

4. Treatment costs

Treatment costs:

Adults with resectable non-small cell lung cancer at high risk of recurrence and whose tumours have PD-L1 expression ≥ 1%; neoadjuvant and adjuvant treatment

Designation of the therapy	Treatment costs/ patient
Medicinal product to be assessed:	
Nivolumab + platinum-based chemotherapy (neoadjuvant treatment) followed by nivolumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Nivolumab + platinum-based chemotherapy	
Nivolumab	€ 17,439.60
Carboplatin	€ 1,452.80 – € 1,729.44
Cisplatin	€ 463.72 – € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 – € 1,439.84
Total (nivolumab + platinum-based chemotherapy; neoadjuvant)	€ 19,118.44 – € 23,449.84[2]
Adjuvant treatment:	
Nivolumab (monotherapy)	
Nivolumab	€ 75,571.60
Appropriate comparator therapy:	
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)	
Neoadjuvant treatment:	
Pembrolizumab + platinum-based chemotherapy	
Pembrolizumab	€ 18,721.56
Carboplatin	€ 1,452.80 – € 1,729.44
Cisplatin	€ 463.72 – € 573.76
Docetaxel	€ 1,960.28
Gemcitabine	€ 1,859.36
Paclitaxel	€ 3,823.88

[2] The lower limit of the range results for nivolumab in combination with cisplatin and vinorelbine. The upper limit of the range results for nivolumab in combination with carboplatin and pemetrexed.

Designation of the therapy	Treatment costs/ patient
Pemetrexed	€ 4,280.80
Vinorelbine	€ 1,153.28 – € 1,439.84
Total (pembrolizumab + platinum-based chemotherapy; neoadjuvant)	€ 20,400.40 – € 24,731.80[3]
Adjuvant treatment:	
Pembrolizumab (monotherapy)	
Pembrolizumab	€ 60,845.07 – € 65,525.46

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 October 2025)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Medicinal product to be assessed:					
Nivolumab + platinum-based chemotherapy (neoadjuvant treatment) followed by nivolumab as monotherapy (adjuvant treatment)					
Neoadjuvant treatment:					
Nivolumab + platinum-based chemotherapy					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	4	€ 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation	€ 100	1	4	€ 400

[3] The lower limit of the range results for pembrolizumab in combination with cisplatin and vinorelbine. The upper limit of the range results for pembrolizumab in combination with carboplatin and pemetrexed.

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
	containing cytostatic agents				
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Adjuvant treatment:					
Nivolumab (monotherapy)					
Nivolumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	13	€ 1,300
Appropriate comparator therapy:					

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pembrolizumab + platinum-based chemotherapy (neoadjuvant treatment) followed by pembrolizumab as monotherapy (adjuvant treatment)					
Neoadjuvant treatment:					
Pembrolizumab + platinum-based chemotherapy					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	2 – 4	€ 200 – € 400
Carboplatin	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Cisplatin	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400
Gemcitabine	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	2	8	€ 800
Paclitaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	4	€ 400

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Pemetrexed	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 100	1	4	€ 400
Vinorelbine	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	2	8	€ 800
Adjuvant treatment:					
Pembrolizumab (monotherapy)					
Pembrolizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 100	1	7 - 13	€ 700 – € 1,300

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

<u>Adults with resectable non-small cell lung cancer at high risk of recurrence and whose tumours have PD-L1 expression ≥ 1%; neoadjuvant and adjuvant treatment</u>

– No medicinal product with new active ingredients that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. **The resolution will enter into force on the day of its publication on the website of the G-BA on 4 December 2025.**

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 4 December 2025

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken